Remarks/Arguments:

With this amendment, claims 1, 14, 19, and 30-45 are pending.

The applicants respectfully submit that the claims before the current Examiner contain specific features that were not in the claims reviewed by the previous Examiner and the Board. These additional features, which impart further patentability to the claims, were added by the applicants' preliminary amendment dated May 14, 2004 (support for which is discussed in detail below). In addition, the applicants also submit an Inventor's Declaration under 37 C.F.R. § 1.132 providing additional grounds for patentability that was also not presented to the previous Examiner or Board. With these amendments, the Inventor's Declaration, and the foregoing arguments, the applicants submit that the pending claims are in a condition for allowance and respectfully request early notification to that effect.

I. The Present Invention

A. Clarification of Terminology

For clarity, the applicants explain the terms "soft" and "hard segments" as recited in the claims. The claims recite "a core of a segmented polymer; the segmented polymer has soft segments and hard segments." The language of "hard" and "soft segments" was particularly chosen because it is well-established in the fiber art as explained in U.S. Patent No. 3,071,557, which is incorporated by reference into the instant application at page 5, lines 16-20. As explained in more detail in the Inventor's Declaration, an elastomeric fiber is substantially a linear polymer constructed from a chain of repeating chemical structures. The linkage mechanism between the repeating chemical structures is referred to by those skilled in the art as the backbone of the polymer. In typical elastomeric fibers, for example Spandex®, there are two predominant linkages: a polyether and polyurethane linkage. One skilled in the art understands that the "soft" segment of a fiber core refers to groups of polymer chains that are rich in polyether linkages along their backbone. Likewise, one skilled in the art understands that "hard segments" of a fiber core refer to groups of polymer chains that are rich in polyurethane linkages along their backbone. To better understand the present invention, the accompanying Inventor's Declaration visually depicts and describes, at a macromolecular level, an exemplary elastomeric fiber core having "hard segments " within a "soft" section. The applicants emphasize the chemical structure of an elastomeric fiber compared to a conventional nylon, Teflon®, or cellulose fiber, as one of the distinguishing factors for patentability of the present invention.

B. Novelty

The present invention is directed to chemically active fiber compositions as a delivery system for chemotherapeutic agents useful in dental hygiene products. An exemplary use of

the fiber of the present invention includes dental floss. As further explained in the Inventor's declaration, a dental floss constructed with the fiber of the present invention is a single fiber ("a fiber") dental floss having a denier value of between about 40 to 40,000. The fiber has a structural composition of a soft section that has dispersed within it, hard segment sections. The hard segment sections are linked chemically by covalent bonds to the soft section and give the fiber its elasticity. (See page 4, lines 3-12 of the present application). The elasticity of the fiber allows it to be stretched, which changes the fiber diameter depending on the amount of stretching force. The fiber returns to its original diameter with release of the stretch. (See page 6, lines 4-7 of the present application).

As noted in the attached Inventor's Declaration, contrast the elastomeric polymer fiber of the present invention with that of a typical nylon, Teflon®, or cellulose fiber. First, an elastomeric polymer fiber is generally quite large when compared to conventional fibers. As claimed, the fiber has a denier value of between 40 to 40,000. As provided in the Inventor's Declaration at paragraph 10, a typical nylon fiber has a denier value of between 15-18. For a sense of scale, a single fiber of an elastomeric polymer may have a similarly sized diameter as that of a yarn of nylon, which consists of hundreds or even thousands of individual nylon fibers[1]. Additionally, the elastomeric polymer fiber of the present invention has a core comprising a soft section having hard segments covalently bonded to the soft section (illustrated in the Inventor's Declaration and described in Part I(A) above). In contrast, nylon, Teflon®, or cellulose fibers have a core structure that consists entirely of hard segments. As explained in more detail in paragraphs 6-10 of the Inventor's Declaration, because nylon, Teflon®, or cellulose fibers consist of essentially hard segments, they are generally inelastic to stretch and impervious to absorption of chemicals.

The ease at which a chemotherapeutic agent may be imbibed to the elastomeric polymer fiber of the present invention is another novel and nonobvious aspect of the invention. To imbibe the fiber with a chemotherapeutic agent, the agent is dissolved in a hot solvent and the fiber is added to the solution. The solution is allowed to cool and, while not intending to be bound to a specific theory, it is understood that the agent is taken up by or dissolved into the structure of the fiber itself. More specifically, the agent is dissolved into the soft section of the core of the fiber. (See pages 11, line 31 through page 12, line 5 of the present application and paragraph 13 of the Inventor's Declaration).

Contrast the action of imbibing of a elastomeric polymer fiber with that of a typical nylon, Teflon®, or cellulose fiber as is described in more detail in the Inventor's Declaration. Because nylon, Teflon®, or cellulose consist only of a hard segment structure, these fibers are

[1] During the prosecution history, there may have been some confusion regarding the use of the terms *fiber* and *filament*. In this response ,for consistency of comparisons, the applicants use the term fiber throughout. For example, the exemplary Spandex dental floss as described herein means the floss is constructed of a single fiber. Contrastingly, the dental floss in Hill et al. is constructed of multiple fibers of nylon.

substantially impervious to adsorption and cannot imbibe agents into their core structure. The mechanism by which chemotherapeutic agents useful in dental hygiene are taken up by nylon, Teflon®, or cellulose fibers is to take multiple fibers and combine them to from a yarn bundle. The yarn bundle has interstitial spaces between the individual fibers. It is in these spaces that the agent is allowed to accumulate. In essence, the agent is trapped within the yarn bundle. By adding more fibers in the yarn bundle, there will be more interstitial spaces between the fiber thus allowing more agent to be accumulated in the yarn bundle. This is in stark contrast to the elastomeric polymer of the present invention, which absorbs the small molecule agent within the structure, i.e., the soft section, of the fiber.

Delivery of the agent from the elastomeric polymer fiber into the oral cavity is accomplished by a mechanism unique to the structure of the elastomeric polymer fiber. Again for example, when the elastomeric polymer fiber is constructed into dental floss, a user of the floss stretches the fiber to the desired degree to place the floss between adjacent teeth. By moving the floss back and forth to remove the unwanted material between the teeth, the floss becomes wet. The imbibed agent is extracted from the floss. Also, the physical stretching of the floss promotes the egress of the agent from the floss. (See page 12, lines 14-27 of the present application and the Inventor Declaration).

II. The Prior Art

A. Burch (U.S. 5,433,226)

Burch discloses a dental hygiene product, and more particularly dental floss comprising a fiber having a core of a segmented polymer. The segments of the polymer are a combination of soft segments, preferably of polyether or polyester type, and of hard segments selected from a group consisting of polyurethane, polyamide, polyimide, and a mixture thereof. The content in hard segments is 5-40% of the polymer by weight. The dental floss of this invention is characterized by exceptionally robust elastic properties, which are necessary to ensure effective and efficient cleaning of teeth (Abstract). Burch fails to disclose or suggest that the fiber composition may be imbibed with a medicament or therapeutic agent.

B. Hill et al. (U.S. 5,098,711)

Hill et al. is directed to a method of treating the oral cavity with dental floss containing a therapeutic agent. At col. 4, Hill et al. address a problem of commercially developed dental flosses manufactured by twisting together 6-10 strands of nylon; they tend to splay, fray, break, or spread out. To prevent splay, conventional commercial flosses sold worldwide are generally manufactured with bonding agents to hold the strands together. (See generally col. 4, lines 17-48). Following the trend to prevent multi-stranded dental flosses from spreading out, Hill states at col. 4, lines 37-41:

> In view of the foregoing, it is not surprising that shread resistant floss has been the basic claim of some floss marketers. The most recent introduction of a Goretex type floss, with its monofilament construction, should prove to the ultimate shred resistant floss. Historically, the typical response to shredding was to develop a "tighter" bonded and smaller diameter floss that did not spread out and did not shred. Waxing was also an option. It is not difficult to see how the "ultimate cord", i.e., monofilament construction, evolved from this approach. The monofilament floss is reported to be easier to use than traditional bonded flosses.

Although a monofilament (i.e., a single fiber) dental floss may be advantageous in that it does not splay, Hill et al. distinguished his dental floss from that of a monofilament floss. Hill et al. found that multi-stranded dental floss can be used to remove plaque and soil from interproximal spaces between teeth, despite its tendency to splay. Hill et al. found that if the multi-strand dental floss is loaded with compositions such as surfactants or various insoluble abrasives, these compositions are released when the dental floss does splay. Loading these composition into the multi-stranded floss is described by Hill et al. at Col. 13, lines 58-66.

> A review of the construction of the preferred floss used in the method of the present invention shows that the <u>compositions employed are contained essentially in the interstitial spaces between the fibers</u> of the floss with minimum composition on the outer surface of the floss. This internal loading of the compositions is achieved by opening up the floss fibers during manufacturing and introducing a melt-emulsion of the compositions of the preferred floss into the space around the opened fibers. (emphasis added).

The mechanism by which the compositions are removed from the dental floss is described at col. 8, lines 14-21:

> [T]he loaded floss of the present invention spreads out during use to obtain the separate mechanical action of the many filaments.
>
> This spreading out during flossing, also triggers the release mechanism which discharges most of the load interproximally during flossing, i.e., up to about 80% by weight.

Further, Hill et al. states at col. 8, lines 26-29:

> Release of the load leaves spaces in the floss which tend to take up and hold some of the microscopic substances dislodged during flossing.

> These "captured" substances can be easily observed in the "spent" floss.

Thus, Hill et al. concludes at Col. 13, line 67 to Col. 14, line 4 that:

> The preferred floss used in the method of the present invention is unique in its capacity to release the "loaded" compositions interproximally. Unexpectedly, the property of releasing these compositions correlates with the opening up and/or flattening of the treated floss strands during flossing.

C. Erickson et al. (U.S. 5,499,917)

Erickson et al. is directed to a dental isolation dam with a plurality of elastic fibers arranged in a rectangular, crisscrossed pattern between impervious films. The dental dam has a hole punched through it such that the dam may be slid over a tooth, for example, a problem tooth having a cavity. The fibers enable the dam to be easily placed, and, once released, clinch around the neck of the isolated problem tooth. The dental dam serves to protect surrounding teeth from moisture and contamination while a dentist is working on the problem tooth. The fibers impart the elastic properties to the dental dam such that the dam is secured around a tooth. The remaining fibers in the dental dam do not contact the oral cavity, but are placed between the layers of impervious materials that comprise the dam.

III. The Office Action Rejections

The Office Action rejects claims 1, 10, 14, and 19 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action rejects claims 1, 10, 14, 19, and 30-45 as unpatentable under 35 U.S.C. § 103(a) over Burch (U.S. 5,433,226) in view of Hill et al. (U.S. 5,098,711) in further view of Erickson et al. (U.S. 5,499,917).

IV. Response

A. Support for Amended Claims

The Examiner rejects claims 1, 10, 14, and 19 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement in that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant are that the inventors, at the time the application was filed, had possession of the claimed invention. The applicants respectfully disagree and request the Examiner's reconsideration.

The MPEP § 2163.06 states that information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter. This includes the claims as originally filed.

The applicants do not understand the rejection and have called the Examiner to clarify the rejection. The Examiner did not substantively discuss the rejection with the applicants' representative, Christian M. Bauer. Thus, the applicants still fail to understand the Office Action rejection. Specifically, at page 3 of the Office Action, the first paragraph recites the claim limitations and acknowledges that the specification provides support for the limitation by reciting the page and line number of specification where support for each element is found. Yet in the next two paragraphs designated by the letters (a) and (b) of page 3, the Office Action contends that there is no support for the very same claim limitations.

Notwithstanding the above, the applicants provide the following for support of the amendments made in the preliminary amendment dated 14 May 2004 and herein. Support for these amendments to independent claims 1, 10, 14, and 19 is found in original claims 2 and 4, and on page 6, lines 7-26 of the application. It is submitted that no new matter is introduced by these amendments and new claims. The applicants respectfully submit that the Examiner's rejection is in error. The claim amendments are supported by the original disclosure.

B. Non-obviousness

The Office Action rejects claims 1, 10, 14, 19, and 30-45 as unpatentable under 35 U.S.C. § 103(a) over Burch (U.S. 5,433,226) in view of Hill et al. (U.S. 5,098,711) in further view of Erickson et al. (U.S. 5,499,917). Specifically, the Office Action states:

> Giving broad interpretation to applicant's claims, examiner takes the position that the language used in Patent '711 wherein chemicals and ingredients are introduced or added or loaded into the fibers is for all intent and purposes deemed to be equivalent['s] claim language wherein the fibers are capable of "imbibing" chemotherapeutic agents.

This is essentially the same position taken by the previous Examiner in the Examiner's Reply Brief at page 4, which was discussed in the Board of Patent Appeals Opinion at page 9. The Board's Opinion asserted: "'imbibing' of active ingredient into the interstitial spaces of Hill is equivalent to coating each of the many individual strands (Answer page 4)."

1. Hill et al. does not disclose coating each <u>of the many individual strands.</u>

Hill et. al does not disclose "coating each of the many individual strands" as used by the Board. Hill et al. discloses the use of a "coating substance in the surfactant to avoid foaming," not the act of coating the fibers (see e.g., the claims). Hill et al. uses the word "coating" to describe a layer contained within the surfactant. Hill et al. does not use the word "coating" to described the act of loading of a chemotherapeutic agent into the dental floss. The distinction is set forth at col. 5, lines 35-43 that discloses both a coating and the floss strands containing a chemotherapeutic agent.

> said floss containing a cleaning preparation comprising a surfactant and a coating substance at from between 5 and about 100% by weight of the weight of the floss strands, and optionally further containing up to about 50% by weight of an active chemotherapeutic agent selected from the group consisting of antimicrobials, antibiotics, antioxidants, desensitizers, and anti-tartar agents.

2. Loading a composition into the interstitial spaces of a multiple filament nylon bundle as described in Hill et al. is not equivalent to imbibing a chemotherapeutic agent into a fiber of the present invention.

The MPEP § 2143.03 states that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending there from is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

The fundamental differences between the presently claimed elastomeric polymer fiber and the multi-stranded nylon fiber of Hill et al. are discussed above. The presently claimed invention requires a fiber imbibed with a therapeutically effective amount of the chemotherapeutic agent. Specifically, the claims recite "A fiber comprising... a) the fiber of an elastomeric polymer...in which: the fiber has a core... ." To the fiber is "(b) a therapeutically effective amount of [a] chemotherapeutic agent imbibed in the fiber." (Note that *fiber* is used in the singular.)

As described in the Inventor's Declaration at paragraph 12, the mechanism by which the present invention imbibes the chemotherapeutic agent is vastly different from the description of Hill et al. of how the chemotherapeutic agent is loaded into the dental floss. As discussed in the Inventor's Declaration and above, one skilled in the art would understand that the fibers of Hill et al. are substantially impervious to absorption of small molecules because they consist substantially entirely of "hard segments." The independent claims of the present invention

require, however, a therapeutically effective amount of the chemotherapeutic agent imbibed in the fiber. That is, the small molecule chemotherapeutic agent is absorbed within the fiber structure, i.e., the soft section, of a single fiber itself. It is because of the structural differences between a single fiber of the present invention and the fibers described by Hill et al. the applicants submit that Hill et al. does not teach a drug , medicament, or therapeutic agent in the polymer fibers. More specifically, the disclosure of Hill et al. does not teach how to imbibe a therapeutically effective amount of a chemotherapeutic agent in a single elastomeric fiber. The applicants respectfully submit that the rejection is in error and request the Examiner's reconsideration.

3. The claimed invention requires a denier value of between 40-40,000 and was shown to imbibe a surprising amount of chemotherapeutic agent.

The independent claims require a single fiber having a denier value in the range of 40 to 4,000 and dependent claims recites the fiber imbibing at least about 2, 000 ppm of a chemotherapeutic agent. As shown in Example 1 and further supported by paragraph 17 of the Inventor's Declaration, a fiber of the present invention having a denier value of 540 can absorb 2300 ppm of sodium flouride. Hill et al. does not teach loading an agent into a fiber of that size. As presented in the Inventor's Declarations, a typical single nylon fiber has a denier value of between 15-18. As previously discussed, multiple nylon fibers twisted into a yarn bundle are needed so that they yarn bundle can structurally maintain an agent within the interstitial spaces between individual nylon fibers. For this additional reasons, the applicants submit that Hill et al. does not teach imbibing an elastomeric fiber of the claimed invention.

Moreover, Hill et al. specifically differentiates his dental floss from that of a single fiber dental floss. First, Hill et al. discloses the size difference between single fiber dental floss and his multi-stranded dental floss. At col. 12, lines 14-20 Hill et al. states:

> In a preferred embodiment of the present invention the floss used is nylon, contains between 4 and 8 strands, with a denier between about 500 and 1000 and contains between about 200 and 600 filaments. In a particularly preferred embodiment of the present invention the floss used is nylon, containing 6 strands, has a denier of about 840 and has approximately 408 filaments.

Note that the nylon floss of Hill et al. has a structure of 4 to 8 strands, each strand being comprised of approximately 408 filaments. A proper structural comparison of Hill et al. to the present invention would be to compare the individual strands of Hill et al. with the fiber of the present invention. As such, Hill et al., or any of the other prior art references of record, does

not teach or suggest an agent imbibed into a single fiber (i.e., an agent imbibed into an individual filament).

C. Nonobviousness in view of Erickson et al. (U.S. 5,499,917)

The Office Action cites col. 4, lines 31-37 of Erickson et al. as disclosing medicaments may be added to the films or fibers. As discussed above, Erickson et al. is directed to a flexible dental dam that, in use, is punctured and a tooth is inserted into the puncture so that the tooth can be isolated from surrounding teeth. The elastic fibers are embedded into layers of an impermeable material and serve to maintain the dental dam over the tooth in question. The applicants are hard pressed to find a teaching in the disclosure that the fibers are exposed to the buccal cavity. The Office Action states the motivation to combine Erickson et al. with the prior art of record:

> lies in the fact that one of ordinary skill would be undoubted to find it useful or desirable and indeed beneficial to add chemotherapeutic agents to the dental fibers in order to control dental infection and dental disease through the application of said dental floss made of fibers having known dental prophylactic or chemical agents impregnated therein as this was suggested by Erickson et al.

The MPEP § 2431.01 states in part: "It is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). The applicants submit that a reference of a dental dam having imbedded fibers within layers of the dental dam and an unsupported statement that compositions, including medicaments, can be added to the films or fibers as desired are not sufficient teachings for one of ordinary skill in the art to make the combination with the other prior art of record. Moreover, a statement that "one of ordinary skill would be undoubted to find it useful or desirable and indeed beneficial to add chemotherapeutic agents" relies on the level of skill in the art to provide the motivation to combine Erickson et al. with the other prior art of record. The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Thus, the applicants submit that the suggested combination of Erickson et al. with the other prior art of record is improper and does not set forth a *prima facia* case for obviousness. Reconsideration is respectfully solicited.

V. Conclusion

The Examiner states that Burch does not disclose the use of a drug, medicament, or therapeutic agent in the polymer fiber. With reference to claim 1, the applicants thus submit that Burch does not disclose the claimed limitation where "a therapeutically effective amount of the chemotherapeutic agent imbibed in the fiber... ." To form a proper prima *facia case* for obviousness, the Examiner must find a reference that teaches what Burch fails to disclose. The Examiner contends that the disclosure of Hill et al. describing a mechanism by which multistranded dental floss (i.e., dental floss comprising from 6-12 individual fibers that are wound or twisted together) (col. 6, lines 34-36) loaded with compositions in the interstitial spaces between the strands of fibers (col. 13, lines 58-66) teaches what Burch fails to disclose. The applicants respectfully disagree and request the Examiner's reconsideration.

Even if, for arguments sake, Hill et al. or another reference discloses an individual fiber imbibed with a therapeutic agent, the applicants submit unexpected results for the amount of agent that a single elastomeric polymer of the present invention can imbibe. With the amendments to claim 1, the applicants submit that these experimental results are commensurate with or predictive of results commensurate in scope with the claimed subject matter. For these additional reasons, the applicants submit the pending claims are novel and unobvious in view of the cited references.

The applicants request the Examiner's reconsideration in light of the arguments presented above and the attached Inventor's Declaration. In view of the lengthy prosecution, the applicants request a telephonic interview with the Examiner and will contact the Examiner to schedule such an interview.

Respectfully submitted,

Bruce M. Monroe, Reg. No. 33,602
Christian M. Bauer, Reg. No. 51,443
Attorneys for Applicants

Dated: December 7, 2004

CMB/dlk

RatnerPrestia
P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500
Fax: (302) 778-2600

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

B_W:\BUR\020\RCE_AMEND01.DOC

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: December 7, 2004